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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,103	11/12/2003	Douglas Craig Scott	9118M2	5133
27752 7590 08/31/2010 THE PROCTER & GAMBLE COMPANY Global Legal Department - IP Sycamore Building - 4th Floor 299 East Sixth Street CINCINNATI, OH 45202				
EXAMINER GEMBEH, SHIRLEY V				
ART UNIT 1628		PAPER NUMBER		
MAIL DATE 08/31/2010		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/706,103

Applicant(s)

SCOTT ET AL.

Examiner

SHIRLEY V. GEMBEH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/19/10 has been entered.
2. Applicant's arguments filed 4/19/10 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-4 and 8-17 are pending in this office action.
5. The rejection of claims 1-4 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiyoshige et al. (US 4,689,221) and Lawlor (US 6,706,256) is withdrawn because of the amendment to the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 8-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kleinberg et al. (US Patent 6,436,370) in view of Coll-Palagos et al. (US Patent 4,309,409) for the reasons made of record in Paper No. 20100419 and as follows.

Applicant argues that “[t]o establish a prima facie case of obviousness under §103, the Examiner has the burden of showing, by reasoning or evidence, that: 1) there

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is some suggestion or motivation, either in the references themselves or in the knowledge available in the art, to modify that reference's teachings; 2) there is a reasonable expectation on the part of one of ordinary skill in the art that the modification or combination has a reasonable expectation of success; and 3) the prior art references (or references when combined) teach or suggest all the claim limitations. MPEP §2145. Applicants submit that the burden of a prima facie case of obviousness has not been met due to a failure of the prior art references teach or suggest all the claim limitations"

In response to item 1, "there is some suggestion or motivation, either in the references themselves or in the knowledge available in the art, to modify that reference's teachings".

Kleinberg teaches an oral composition (i.e., a chewing gum) comprising abrasives/polishing agents (i.e., calcium carbonate or arginine bicarbonate) wherein they necessarily exhibit adhesive properties from 20-60%, and may also be in other forms such as paste, mouth washes and gels.

Coll-Palagos is added because their composition of an oral dentifrice in a dental cream comprises polishing material zinc oxide (i.e., water insoluble) that may be present in the amount ranging from 40-67% (see col. 2, lines 5-6). Because Kleinberg's teaches their formulation may be in the form of chewing gum, tablet, mouth washes and gels and paste, one of ordinary skill in the art would have been motivated to substitute Kleinberg's composition comprising the polishing agent of calcium carbonate with zinc oxide of Coll-Palagos into Kleinberg's chewing gum formulation. It should be noted that this a composition claim, Applicant's reason or motivation to modify the reference may

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often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (see MPEP 2144).

Item 2, there is a reasonable expectation on the part of one of ordinary skill in the art that the modification of Kleinberg's composition to include Coll-Palagos compositions would be expected to give a reasonable expectation of success because both compositions are directed to a dentifrice product that comprises a polishing agent (i.e., a retentive agent). And also because "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In *re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), and "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. (see MPEP 2112.01).

With regards to item 3, it is evident that when Kleinberg and Coll-Palagos are combined the claimed limitations of the instant application are met.

Additionally, the density is 59,000-76,000 per square millimeter is not recited in the claim. However, the recitation that Coll-Palagos teaches that zinc oxide is in the amount of 0.05%-2.0% is correct. It should be noted that Coll-Palagos also teach that zinc oxide from 13-80% and 40-67% are preferred (see col. 2, lines 1-5).

Applicant's arguments have been fully considered but they are not persuasive. for the reasons given above and re-iterated below. Furthermore MPEP2112.1 teaches As stated in the MPEP 2112.01 "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Additionally the herein-claimed properties of "visible on 2-3 molar....for 5-6- minutes after chews...." do not lend patentability to the claims because they are inherent properties of the formulation that would be produced following the suggestions of the prior art. See MPEP § 2145, paragraph II, which states, "Granting a patent on the discovery of an unknown but inherent function..." would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art", and, "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious."

In summary

Kleinberg teaches a dental oral composition (i.e., a chewing gum or a tablet) may comprise abrasives/polishing agents from 20-60%, a pH buffer (i.e., arginine bicarbonate which ensures pH neutrality), a surfactant (i.e., sodium lauryl sulfate) and an oral care active (i.e., a fluoride) as required by instant claim 1 (see col. 5, lines 29-33, col. 6, lines 16-20, 27-34, and 46-50) for the treatment of dental conditions such as

dental sensitivity (as required by instant claim 14). Kleinberg also teaches that the oral active care is a fluoride ion source that provides approximately 10-1500 ppm of fluoride ion (see col. 6, lines 18-20, as required by instant claims 8 and 9). Since Kleinberg teaches a chewing gum, it is reasonable that the chewing gum is in a solid unit dosage form (as required by instant claim 10). With regards to instant claim 13, once the chewing gum is being placed in the oral cavity and chewed it intrinsically would buffer the oral cavity saliva to a pH of above neutrality as high as pH 9 (see col. 5, lines 29-34) wherein the buffer is an amino acid buffer (i.e., arginine bicarbonate, as required by instant claim 11, see col. 5, lines 29-34). It is reasonable that once the chewing gum comprising abrasives/polishing agents from 20-60% is chewed, intrinsically the polishing/abrasive agents will adhere to the teeth surface for a period of time (as required by instant claims 1, 3, 4, 13 and 16) and the mouth/oral cavity saliva will be buffered as required by instant claim 13-14 and 16 . Because Kleinberg does not teach their oral composition as effervescent, it is reasonable to conclude that Kleinberg is a non-effervescent composition (i.e., as it relates to claim 1).

It should be noted that *In re Harris*, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005) found that a claimed alloy was upheld as obvious over a prior art alloy that taught ranges of weight percentages overlapping, and in most instances completely encompassing, claimed ranges. See MPEP 2144.05.

However Kleinberg fails to specifically recite what comprises their abrasives or polishing agents. Coll-Palagos et al. is therefore introduced.

Coll-Palagos et al. teach an oral dentifrice formulation comprising an abrasive zinc oxide (i.e., water insoluble) that may be present in the amount ranging from 40-67%, having a pH adjuster (i.e., phosphate buffer), a fluoride ion source (SnF_2KF), a surfactant (i.e., sodium lauryl sulfate) (as it relates to claims 1, 8, 10-11, see col.2, lines 1-6, 24-30 and col. 3, lines 38 and 55-62). With regards to the limitation of claims 1-2, 15 and 17 wherein the retentive agent has a water solubility of 1g/30 g at 25°C, this reasonably is an inherent property of the compound, because products of identical chemical composition can not have mutually exclusive properties (see MPEP 2112.01). With regards to instant claim 4, once the composition containing a pH adjuster, an active oral care, a surfactant and a water insoluble retentive agent (abrasive/polishing agents as known in the art) is placed in the mouth, reasonably 0.5%-20% by weight of the composition will deposit on the tooth surface. Because Coll-Palagos does not teach their oral composition as effervescent, it is reasonable to conclude that Coll-Palagos is a non-effervescent composition (i.e., as it relates to claim 1). Because, Coll-Palagos teaches zinc oxide in their composition (i.e., identical compounds to the claimed invention), they intrinsically would have the same solubility of 1g/30g at 25°C or less than 1g/100g at 25°C. Therefore the limitations of claims 1- 2, 12 and 15-17 are met.

One of ordinary skill in the art would also expect the composition when chewed will be visible on 4-5 molars for 5-60 minutes because the same agents used in Coll-Palagos are the same recited in the claim 1.

However, Coll-Palagos fails to teach a solid dosage form.

Even though Kleinberg fails to recite the specific abrasive used in the composition, one of ordinary skill in the art would have been motivated to expand the oral solid chewable dentifrice composition taught by Kleinberg to include zinc oxide of Coll-Palagos because Kleinberg teaches generically that a dental oral composition (i.e., a chewing gum or a tablet) may comprise abrasives/polishing agents from 20-60%.

With regards to claim 12, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container. See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of *In re Haller*, it is stated that: "whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of patentability is concerned . . . In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new".

Moreover, the claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

Nevertheless, in the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus because claim 12 is drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to this rejection under 35 USC 103.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached on 571-272-2919. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
8/25/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649